

AMENDMENT

IN THE CLAIMS

Please amend the claims as shown below.

1. (previously presented) A process for making torsemide modification II comprising torsemide modification I at less than about 0.5 weight%,

comprising the steps of:

- (a) adding a crude torsemide modification II to a solvent mixture comprising acetonitrile and water;
- (b) isolating torsemide modification I;
- (c) suspending the torsemide modification I of step (b) in water to form a solution;
- (d) adjusting the solution of step (c) to a pH of about 10 ± 0.2 ;
- (e) filtering the solution of step (d);
- (f) adjusting the solution of step (e) to a pH of 6.25 ± 0.2 ; and
- (g) isolating torsemide modification II comprising torsemide modification I at less than about 0.5 weight%.

2. (currently amended) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipient ~~excipients~~ wherein the ~~excipients have~~ excipient has a low moisture content.

3. (currently amended) The stable pharmaceutical formulation of claim 2, wherein the excipient ~~further comprising the excipients~~ having a low moisture content is selected from the group consisting of lactose anhydrous, crospovidone, povidone, microcrystalline cellulose, and magnesium stearate.

4. (original) The stable pharmaceutical formulation of claim 2 comprising torsemide modification II in an amount of about 2.5 mg to about 200 mg per tablet.

5. (original) The stable pharmaceutical formulation of claim 4 comprises torsemide modification II in an amount of about 2.5 mg, about 5 mg, about 10 mg, about 20 mg or about 100 mg per tablet.

6. (currently amended) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II wherein no more than 15% of the torsemide modification II does not substantially rearrange into another form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity over time upon storage.

7.-8. (canceled)

9. (currently amended) The stable pharmaceutical formulation of claim 6 wherein no more than 15% of the torsemide modification II does not substantially rearrange into torsemide modification I over time upon storage under stress conditions for at least 3 months.

10. (original) The stable pharmaceutical formulation of claim 9 wherein not more than 5% of the torsemide modification II rearranges into torsemide modification I.

11. (currently amended) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing ~~trace amounts of~~ torsemide modification I at trace amounts, wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I, and wherein the trace amounts of torsemide modification I is about 0.5 weight% to about 2 weight%.

12. (original) The stable pharmaceutical formulation of claim 11 wherein the torsemide modification II comprises about 0.5 to about 2% (w/w) of torsemide modification I.

13. (original) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200μ.

14. (original) The stable pharmaceutical formulation of claim 13 wherein the particle size distribution is such that 100% is below 100 μ .
15. (original) The stable pharmaceutical formulation of claim 14 wherein the particle size distribution is such that 100% is below 50 μ .
16. (previously presented) Torsemide modification II comprising torsemide modification I at less than about 0.5 weight%.
17. (previously presented) The torsemide modification II of claim 16 which is a stable polymorphic form of torsemide.
18. (currently amended) The torsemide modification II of claim 17, wherein no more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.
19. (canceled)
20. (previously presented) The torsemide modification II of claim 18 which is in the form of fine crystals.
21. (previously presented) The torsemide modification II of claim 18 wherein not more than 15% of the torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.
22. (previously presented) The torsemide modification II of claim 21 wherein not more than 10% of the torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.

23. (previously presented) The torsemide modification II of claim 17 which is further characterized by having a particle size distribution such that 100 % is below 200 μ .
24. (previously presented) The torsemide modification II of claim 23 which is further characterized by having a particle size distribution such that 100% is below 100 μ .
25. (previously presented) The torsemide modification II of claim 24 which is further characterized by having a particle size distribution such that 100% is below 50 μ .
26. (previously presented) Torsemide modification II comprising torsemide modification I at less than about 0.5 weight% produced according to the process of claim 1.
27. (previously presented) The torsemide modification II of claim 26 which is a stable polymorphic form of torsemide.
28. (currently amended) The torsemide modification II of claim 27; wherein not more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.
29. (canceled)
30. (previously presented) The torsemide modification II of claim 28 which is in the form of fine crystals.
31. (canceled)
32. (currently amended) The torsemide modification II of claim ~~28~~ 31 wherein not more than 10% of the high purity torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.

33. (previously presented) The torsemide modification II of claim 32 which is further characterized by having a particle size distribution such that 100 % is below 200 μ .

34. (previously presented) The torsemide modification II of claim 33 which is further characterized by having a particle size distribution such that 100% is below 100 μ .

35. (previously presented) The torsemide modification II of claim 34 which is further characterized by having a particle size distribution such that 100% is below 50 μ .

36.-38. (canceled)

39. (currently amended) The torsemide modification II of claim 22 38, wherein not more than 5% of the torsemide modification rearranges into torsemide modification I during storage at 40°C and 75% relative humidity for at least 3 months.

40.-42. (canceled)

43.(currently amended) The torsemide modification II of claim 32 42, wherein not more than 5% of the torsemide modification rearranges into torsemide modification I during storage at 40°C and 75% relative humidity for at least 3 months.

44.(previously presented) The torsemide modification II of claim 16, wherein not more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

45.(previously presented) The torsemide modification II of claim 44, wherein not more than 10% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

46.(previously presented) The torsemide modification II of claim 44, wherein not more than 5% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

47.(previously presented) The torsemide modification II of claim 44, wherein not more than 2% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

48.(previously presented) The torsemide modification II of claim 16, wherein not more than 15% of the torsemide modification II rearranges into torsemide form 1 during storage at 40°C and 75% relative humidity for at least 3 months.

49.(previously presented) The torsemide modification II of claim 48, wherein not more than 10% of the torsemide modification II rearranges into torsemide form 1 during storage at 40°C and 75% relative humidity for at least 3 months.

50. (new) The stable pharmaceutical formulation of claim 11, the torsemide modification II containing torsemide modification I at trace amounts, wherein the trace amounts is about 0.5 weight% to about 2 weight%, and wherein the formulation further comprises a combination of excipients selected from lactose anhydrous NF, crospovidone NF, providone NF, povidone USP and microcrystalline cellulose NF.

51. (new) The stable pharmaceutical formulation of claim 50, containing a moisture content of 0.5-1.5%.